

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor's Name

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's name from Phoenix Scientific, Inc., to IVX Animal Health, Inc. In order to improve the accuracy of the regulations, erroneous entries for Phoenix Pharmaceutical, Inc., are also being removed at this time.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6967, e-mail: david.newkirk@fda.gov.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, has informed FDA that it has changed its name to IVX Animal Health, Inc. Accordingly, the agency is amending the regulations in § 510.600 (21 CFR 510.600) to reflect the change.

In addition, FDA has noticed that Phoenix Pharmaceutical, Inc., is no longer a sponsor of an approved new animal drug application. At this time, § 510.600 is amended to remove entries for this sponsor. This action is being taken to improve the accuracy of the regulations.

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This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entries for “Phoenix Pharmaceutical, Inc.” and “Phoenix Scientific, Inc.”, and by alphabetically adding a new entry for “IVX Animal Health, Inc.”; and in the table in paragraph (c)(2) by removing the entry for “057319” and by revising the entry for “059130” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
IVX Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503.	059130

(2) * * *

Drug labeler code	Firm name and address
059130	IVX Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503

Dated: November 15, 2005
November 15, 2005.

Steven D. Vaughn

Steven D. Vaughn,
Director, Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

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